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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

NOV 12 2004

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 330

Complete if Known	
Application Number	09/961,414
Filing Date	September 25, 2001
First Named Inventor	HIRAI ET AL.
Examiner Name	V. Ford
Art Unit	1645
Attorney Docket No.	12218/1

METHOD OF PAYMENT (check all that apply)

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3. ADDITIONAL FEES

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)
1051	130	2051	65
1052	50	2052	25
1053	130	1053	130
1812	2,520	1812	2,520
1804	920*	1804	920*
1805	1,840*	1805	1,840*
1251	110	2251	55
1252	420	2252	210
1253	950	2253	475
1254	1,480	2254	740
1255	2,010	2255	1,005
1401	330	2401	165
1402	330	2402	165
1403	290	2403	145
1451	1,510	1451	1,510
1452	110	2452	55
1453	1,330	2453	665
1501	1,330	2501	665
1502	480	2502	240
1503	640	2503	320
1460	130	1460	130
1807	50	1807	50
1806	180	1806	180
8021	40	8021	40
1809	770	2809	385
1810	770	2810	385
1801	770	2801	385
1802	900	1802	900
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SUBTOTAL (3) (\$ 330

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Name (Print/Type)	Zeba Ali	Registration No. (Attorney/Agent)	51,392	Telephone
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANTS : HIRAI, Fumiyasu *et al.*
SERIAL NO. : 09/961,414
FILING DATE : September 25, 2001
FOR : ENTEROTOXIN ADSORBENT, METHOD OF
ADSORPTIVE REMOVAL, AND ADSORPTION
APPARATUS
EXAMINER : V. FORD
GROUP ART UNIT : 1645

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Appellants respectfully submit this Appeal Brief in support of their appeal from the final rejection in this application.

Real Party in Interest

The real party in interest is the Assignee of record, Kaneka Corporation.

Related Appeals and Interferences

No other appeals or interferences are known to the Appellants, or to the Assignee or the Assignee's legal representatives involved in the prosecution of this application that will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

Status of Claims

The application was originally filed with 5 claims. During prosecution, claims 6 through 10 were added and claims 1-3 and 5 were canceled. Therefore, claims 4 and 6-10 are pending. The Appellants appeal the rejection of all pending claims. The pending claims are reproduced in Appendix A of this brief.

Summary of Invention

The present invention is directed to a method for adsorptive removal of enterotoxins in bodily fluid. Enterotoxins are toxins produced by *Staphylococcus aureus*, among other bacteria, which have various biological activities such as emetic, pyrogenic and mitogenic activities, inducing symptoms of food poisoning or being causative of toxic shock syndrome (TSS) (See page 1, lines 14-17). The method for the removal of such enterotoxins, as recited in claims 4 and 6-10, includes using an adsorbent comprising a compound with a log P value of not less than 3.00, as immobilized on a water-insoluble carrier. P represents a partition coefficient in an octanol-water system (See claim 1).

The present application describes screening for compounds for adsorption of enterotoxins by immobilizing compounds having various log P values on a water-insoluble carrier and evaluating their respective adsorptive affinity for enterotoxins. (See page 5, lines 32-35). Appellants found that compounds having a log P value of not less than 3.00 are effective in the adsorption of enterotoxins, while compounds with log P values of less than 3.00 do not appreciably adsorb enterotoxins. For example, as shown from a comparison of Example 1 and Example 2 of the present specification, the adsorbing property in Example 1 using n-hexadecylamine (log P=7.22) is better than that obtained in Example 2 using n-octylamine (log P=2.90). (See page 12, line 29 to page 13, line 17; and Table 1, page 14 at line 10).

Issues

Are claims 4 and 6-10 rendered obvious under 35 U.S.C. 103(a) by Nagaki *et al.* Journal of Med. Microbiol., Vol. 38, pages 354-359 (1993) ("Nagaki") in view of EP 0993834 to Hirai *et al.* ("Hirai").

Grouping of the Claims

The claims are addressed collectively.

Argument

A. There is no Motivation or Suggestion to Combine the Teachings of Nagaki and Hirai

Hirai describes a method for adsorbing toxic shock syndrome toxin-1 (TSST-1). However, Hirai does not mention enterotoxins at all, as recited in claims 4 and 6-10.

Nagaki describes a method for adsorbing enterotoxin A but Nagaki does not disclose using adsorbents comprising a compound having a log P value of not less than 3.00, as recited in claims 4 and 6-10. Nagaki only describes that enterotoxins and TSST-1 "are structurally closely related." In the Office Action of March 19, 2004 (page 6), the Examiner stated that one of skill in the art would reasonably conclude that TSST-1 and enterotoxins have similar adsorbent properties. However, the Examiner did not specifically point to any support for such a statement either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Indeed, Nagaki merely describes that enterotoxins and TSST-1 "are structurally closely related" and neither Hirai nor Nagaki mentions the relationship between the adsorbent property of enterotoxins and the adsorbent property of TSST-1. Accordingly, Appellants submit that there is no motivation to a person of skill in the art to replace the adsorbent in the adsorptive method for enterotoxin A of Nagaki with the adsorbent of TSST-1 of Hirai.

B. There is No Reasonable Expectation of Success

Appellants submit that there is absolutely no indication in Hirai or Nagaki or in the general knowledge of one of ordinary skill in the art to reasonably conclude that TSST-1 as well as enterotoxins can be removed with the same adsorbent with a reasonable expectation of success. Concerning the relationship between TSST-1 and enterotoxins, Nagaki merely describes that enterotoxins and TSST-1 "are structurally closely related" and Hirai makes absolutely no comparison of enterotoxins and TSST-1. In the chemical field, it is general knowledge that two compounds that are structurally

similar can often have quite different properties. In view of this general knowledge, one of ordinary skill in the art would not have concluded that enterotoxins and TSST-1 have similar adsorbent properties simply from the statement in Nagaki that enterotoxins and TSST-1 are structurally closely related (without in any way describing the relationship between the adsorbent property of enterotoxins and the adsorbent property of TSST-1). Appellants emphasize that structural similarity does not necessarily parallel with adsorbent similarity.

Throughout the Office Actions, the Examiner did not seem to take into account this general knowledge that structurally similar compounds do not necessarily have similar adsorbent properties, and did not point to any support in the references or in the knowledge generally available to one of ordinary skill in the art for otherwise concluding that TSST-1 and enterotoxins have similar adsorbent properties. Instead, the Examiner used the Appellants' disclosure to try to establish this point. Specifically, on page 4-5 of the Examiner's Advisory Action, the Examiner stated:

It should be noted that the adsorbent comprising compounds with log P values of not less than 3.00 as immobilized on a water-insoluble carrier used for the removal of TSST-1 as taught by Hirai et al are the same as the adsorbents used in the claimed method of removing enterotoxins (see page 7 of the instant specification). Therefore, one of skill in the art would reasonably conclude that TSST-1 (an exotoxin) and enterotoxins have similar adsorbent properties and TSST-1 as well as enterotoxins can be removed using an adsorbent comprising a compound with a log P value of not less than 3.00 as immobilized on a water-insoluble carrier with a reasonable expectation of success.

(emphasis in original).

It is well established that the reasonable expectation of success must be found in the prior art, and not in the applicant's disclosure. See In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Indeed, it was the Appellants who demonstrated for the first time in the present application that enterotoxin and TSST-1 show similar adsorbent properties on the claimed adsorbent. Nagaki, as well as Hirai, does not disclose this discovery and one of ordinary skill in the art could not have derived this discovery from the disclosures of Nagaki and Hirai or from the general knowledge at the time the claimed invention was made. Accordingly, based on a proper analysis, Appellants

submit that there is no basis for a reasonable expectation of success that the adsorbent for TSST-1 of Hirai can adsorb enterotoxin A in the method of Nagaki.

Conclusion of Argument

Appellants submit that the Examiner has not met her burden of establishing a *prima facie* case of obviousness against claims 4 and 6-10. Specifically, Appellants submit that there is no motivation for a person of skill in the art to replace the adsorbent in the adsorptive method for enterotoxin A of Nagaki with the adsorbent of TSST-1 of Hirai to produce the claimed invention. Further, there is no reasonable expectation of success that the adsorbent for TSST-1 of Hirai can adsorb enterotoxin A in the method of Nagaki. Appellants respectfully submit that the rejections of the pending claims should be reversed.

Fee Authorization

The Commissioner is authorized to charge the fee for this appeal brief of \$330.00 as set forth in 37 C.F.R. §1.17(c) to Deposit Account No. 11-0600.

Respectfully submitted,
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APPENDIX A

4. A method for adsorptive removal of an enterotoxin in a body fluid which comprises contacting an enterotoxin-containing body fluid with an enterotoxin adsorbent to adsorb and remove the enterotoxin, wherein said enterotoxin is at least one selected from the group consisting of staphylococcal enterotoxins A, B, C1, C2, C3, D, E, G, H, and I, said adsorbent comprising a compound with a log P, in which P represents a partition coefficient in an octanol-water system, value of not less than 3.00 as immobilized on a water-insoluble carrier.
6. The method according to claim 4, wherein said water-insoluble carrier is a water-insoluble porous carrier.
7. The method according to claim 6, wherein said water-insoluble porous carrier has a molecular weight of exclusion limit of 50000 to 600000 for globular protein.
8. The method of claim 4, wherein said compound with a log P value of not less than 3.00 is at least one selected from the group consisting of unsaturated hydrocarbons, alcohols, amines, thiols, carboxylic acids and derivatives thereof, halides, aldehydes, hydrazides, isocyanates, oxirine ring-containing compounds, and halogenated silanes.
9. The method according to claim 4, wherein said compound with a log P value of not less than 3.00 is an amine.
10. The method according to claim 4, wherein said compound with a log P value of not less than 3.00 is hexadecylamine.